



19 September 2024

ASX Announcement

Island Pharmaceuticals presentation for Pitt Street Research Life Sciences Conference 2024

MELBOURNE Australia, 19 September 2024: Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA; Island or the Company**) is pleased to provide a copy of the presentation that will be delivered at the Pitt Street Research Life Sciences Conference 2024 today.

Island's Executive Chairman, Dr Paul MacLeman will provide an update on the company's Phase 2a/b dengue fever trial for its lead asset ISLA-101, and an overview of Island's proposed acquisition of antiviral molecule, galidesivir.

A copy of the presentation is appended to this announcement.

To subscribe to Island's monthly newsletter, [IslandWatch](#), and other forms of email communications, please visit [this page](#) of our website.

Approved for release to the ASX by:

Dr Paul MacLeman
Executive Chairman
Island Pharmaceuticals Ltd
info@islandpharmaceuticals.com

Investors and media, for further information, please contact:

Jane Lowe
IR Department
Mobile: +61 411 117 774
jane.lowe@irdepartment.com.au

About Island Pharmaceuticals

Island (ASX: ILA) is a drug repurposing company, focused on areas of unmet need for antiviral therapeutics to address infectious diseases. Our lead asset is ISLA-101, a drug with a well-established safety profile, being repurposed for the prevention and treatment of dengue² fever and other mosquito (or vector) borne diseases.

If ISLA-101 achieves FDA approval, and certain other criteria are met, Island



may be eligible to obtain a "Priority Review Voucher" at the time of FDA approval. This means that as well as getting approval to manufacture and sell ISLA-101, the Priority Review Voucher (PRV) could permit Island to expedite the FDA approval process for a new drug or sell the PRV in a secondary market.

Island encourages all current investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, whose contact info is housed on the Shareholder Services page of the Company's website.

Visit www.islandpharmaceuticals.com for more on Island.

TARGETING VIRAL THREATS, DEVELOPING LIFESAVING COUNTERMEASURES



**Dr PAUL MacLEMAN,
EXECUTIVE CHAIR**

PITT STREET RESEARCH LIFE SCIENCES CONFERENCE
SEPTEMBER 2024

(ASX: ILA)

DISCLAIMER



This presentation has been prepared by Island Pharmaceuticals Limited (ABN 641 183 842) (**Company or Island Pharmaceuticals**).

Not an offer or financial product advice

The Company is not licensed to provide financial product advice. This presentation is not and should not be considered, and does not contain or purport to contain, an offer or an invitation to sell, or a solicitation of an offer to buy, directly or indirectly any securities, to any person in any jurisdiction to whom or in which such offer or solicitation is unlawful nor shall it (or any part of it), or the fact of its distribution, form the basis of, or be relied on in connection with or act as any inducement or recommendation to enter into, any contract whatsoever relating to any securities. This presentation is for information purposes only and is not a prospectus, product disclosure statement, pathfinder document for the purposes of section 734(9) of the Australian *Corporations Act 2001* (Cth) (**Corporations Act**) or other offer document under Australian law or the law of any other jurisdiction. This presentation does not constitute an invitation to apply for or purchase Securities and does not include any application form for Securities. This presentation does not constitute an advertisement for an offer or proposed offer of Securities. Neither this presentation nor anything contained in it shall form the basis of any contract or commitment and it is not intended to induce or solicit any person to engage in, or refrain from engaging in, any transaction. Nothing in this presentation constitutes legal, financial, tax or other advice. Recipients of the presentation should conduct their own investigation, evaluation and analysis of the business and other data and information set out in the presentation.

Financial data All dollar values are in Australian dollars (\$) or A\$) unless otherwise stated. Any financial data in this presentation is unaudited. **Past performance** The operating and historical financial information given in this presentation is given for illustrative purposes only and should not be relied upon as (and is not) an indication of the Company's views on its future performance or condition. Actual results could differ materially from those referred to in this presentation. You should note that past performance of the Group is not and cannot be relied upon as an indicator of (and provides no guidance as to) future Group performance.

Future performance

This presentation contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "propose", "goals", "targets", "aims", "outlook", "forecasts", "should", "could", "would", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Any indications of, and guidance on, future operating performance, earnings and financial position and performance are also forward-looking statements. Forward-looking statements in this presentation include statements regarding the Company's future growth options, strategies and new products. Forward-looking statements, opinions and estimates provided in this presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions.

Forward-looking statements, including projections, guidance on future operations, earnings and estimates (if any), are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. No representation is given that the assumptions upon which forward looking statements may be based are reasonable. This presentation contains statements that are subject to risk factors associated with the Group's industry. These forward-looking statements may be affected by a range of variables which could cause actual results or trends to differ materially, including but not limited to earnings, capital expenditure, cash flow and capital structure risks and general business risks.

No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including the Company). In particular, but without limitation, no representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward looking statements in this presentation will actually occur. Actual operations, results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. Any forward looking statements in this presentation speak only as of the date of this presentation.

Subject to any continuing obligations under applicable law, the Company disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this presentation to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based.

Nothing in this presentation will under any circumstances create an implication that there has been no change in the affairs of the Group since the date of this presentation.



ASSETS:

- Known small molecules with clinical history
- Mid/late stage clinical or other abbreviated routes
- Open USFDA INDs
- Validated US Govt/military funding support
- Priority Review Voucher eligible

RAPID PATHS TO MARKET

STRATEGIC CHECKLIST



- ✓ Clinical history
- ✓ Small molecule
- ✓ Proven preclinical anti-viral activity
- ✓ Eligible for Priority Review Vouchers
- ✓ National and military preparedness need
- ✓ Probable/confirmed non-dilutive funding to support: military, civilian, NGO
- ✓ Fit for our management and advisory team: mid/late stage drug development, extensive medical countermeasures experience and roles





STRATEGIC CONNECTIVITY BETWEEN ASSETS: ISLA-101 (FENRETINIDE) AND GALIDESIVIR

Both assets:

- Have completed Phase I or later human clinical trials
- Have open Investigational New Drug applications with FDA
- Are antivirals, therefore fast to develop and potential for early licensing if sought
- Supported by governments and military; needed for outbreaks and medical countermeasures
- Priority Review Voucher eligible (multiple options)
- Capable of multiple 'shots on goal': each has many potential disease targets

About ISLA-101



**“About half of the world's
population is now at risk of
dengue with an estimated
100–400 million infections
occurring each year”**

World Health Organisation, 30 May 2024

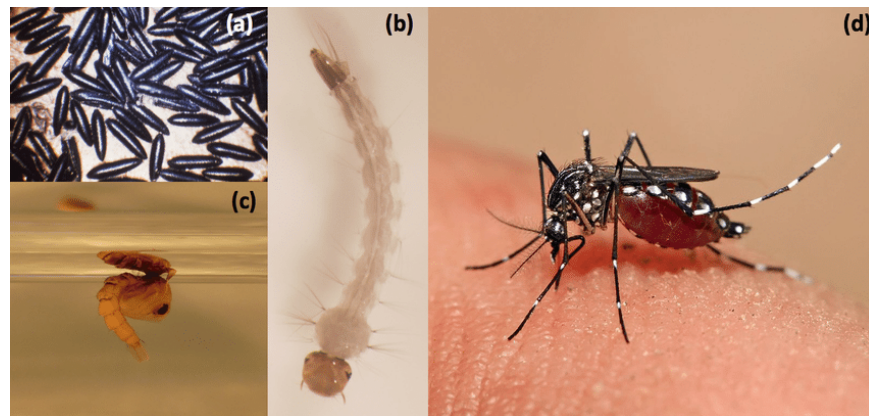


TARGETING KNOWN OR RE-PURPOSABLE DRUGS WITH REDUCED TIME TO MARKET



ISLA-101 – dengue, Zika, Yellow Fever, Chikungunya, other arboviruses

- 45+ human trials of ISLA-101 completed in other indications
- Island's recent Single Ascending Dose study reinforced safety and established the effective human EC50 dose
- Infectious disease, so trial endpoints are rapidly achieved
- Multiple PRV options
- CRADA with US military
- Phase IIa subject screening underway



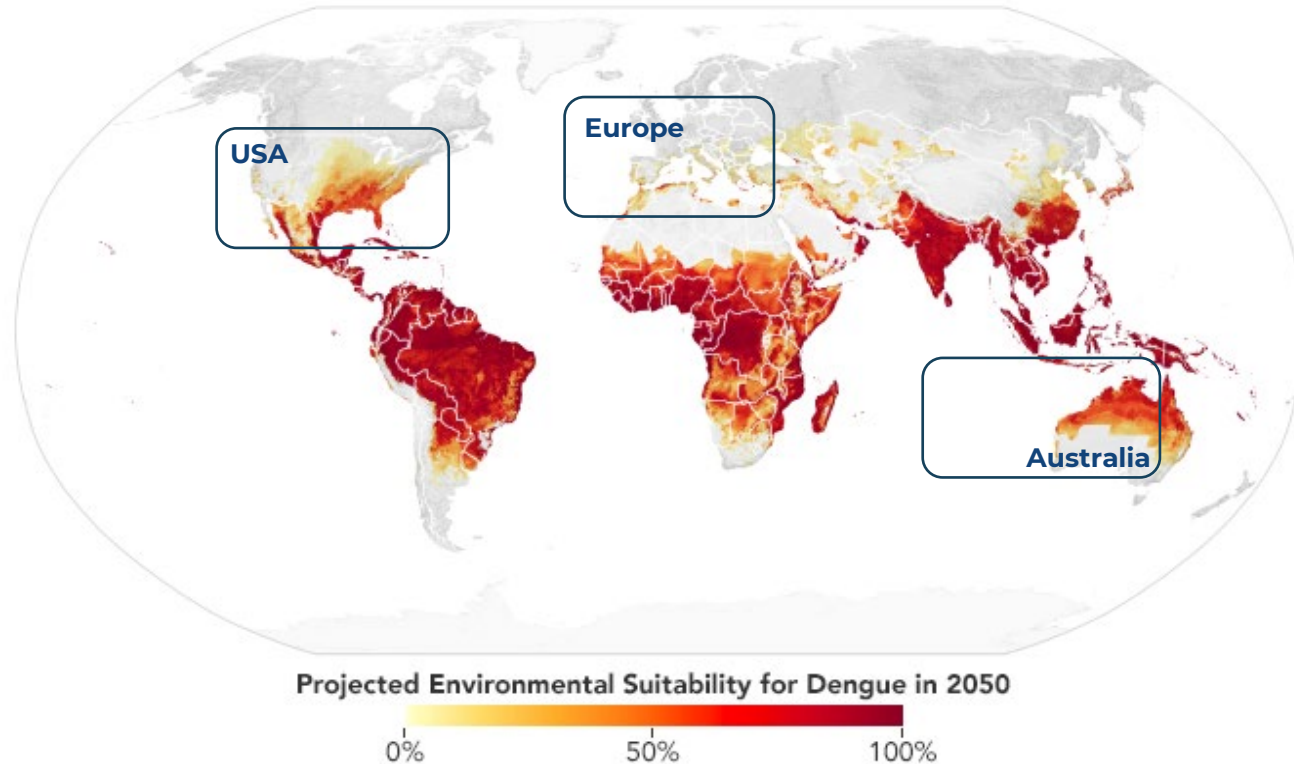
Single Ascending Dose study showed 2-3x bioavailability in fed subjects

Now exploring prophylactic / therapeutic approaches via Phase 2a/b studies under IND

DENGUE IN 2050 – A GLOBAL DISEASE



WHO prediction based on projections of future temperatures, rainfall, and mosquito populations



NASA Earth Observatory map by Lauren Dauphin based on data from Janey Messina, University of Oxford - <https://earthobservatory.nasa.gov/features/disease-vector>

PHASE 2a/b DENGUE (PROTECT) TRIAL STUDY



“**PROTECT**” study- A Phase 2a/b, Randomized, Double blind, Placebo-controlled Dengue Challenge Study – a PROphylactic and TrEatment Challenge Trial



The study will be run at SUNY Upstate Medical University Syracuse, New York.

US\$624k Congressionally Directed Medical Research Programs (CDMRP) grant awarded to The Research Foundation for SUNY to directly support PROTECT study.

Phase 2a/b trial protocol: 2 cohorts

1. Prophylactic Cohort- 2A: 4 subjects randomized 3:1
2. Therapeutic Cohort: 2B: 10 subjects randomized 8:2

Inclusion

- Healthy male and female, women not of childbearing potential
- Age 18-55
- Willing to use contraception for the duration of the study
- Informed consent

Exclusion

- Female: Known or suspected pregnancy
- Men: Who intend to father a child within 90 days after dosing
- Prior infection with HIV, HCV, Flaviviruses
- Current, or a history of, auto-immune disease

Primary endpoint

- Assess the effect of ISLA 101 on viraemia and clinical signs and symptoms after challenge with DENV-1-LVHC

Secondary endpoints

- Characterize the clinical, immunologic and virologic responses following ISLA 101 after challenge with DENV-1-LVHC
- Assess the safety of ISLA 101 in the challenge with DENV-1-LVHC

PHASE 2a/b CLINICAL TRIAL DESIGN



Phase 2a/b trial protocol: 2 cohorts

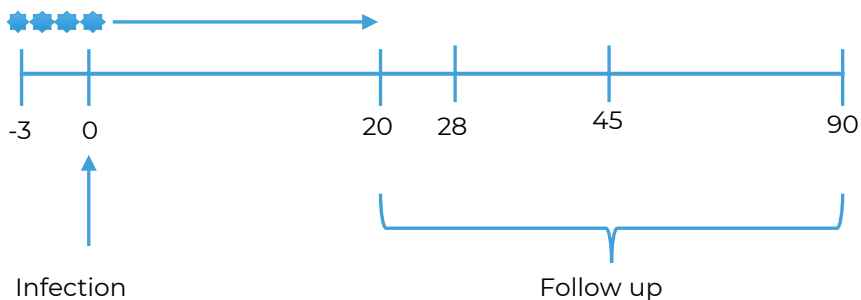
1. Prophylactic Cohort- 2a (left): 4 subjects randomized 3:1
2. Therapeutic Cohort: 2b (right): 10 subjects randomized 8:2

Key near-term milestones:

- Ethics approval received in August 2024, patient screening began in early September, with dosing expected to start at the end of this month
- Phase 2a read out expected by the end of 2024
- Phase 2b cohort dosing expected to commence in Jan 2025

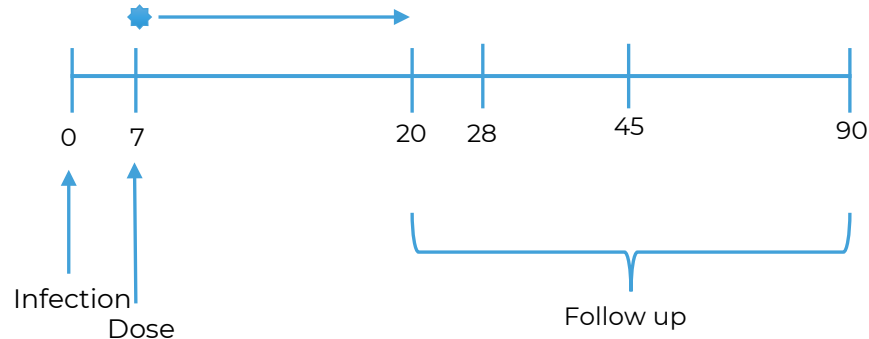
Phase 2a: Prophylactic (preventative) cohort

Administer ISLA-101 daily



Phase 2b: Therapeutic (treatment) cohort

Administer ISLA-101 daily



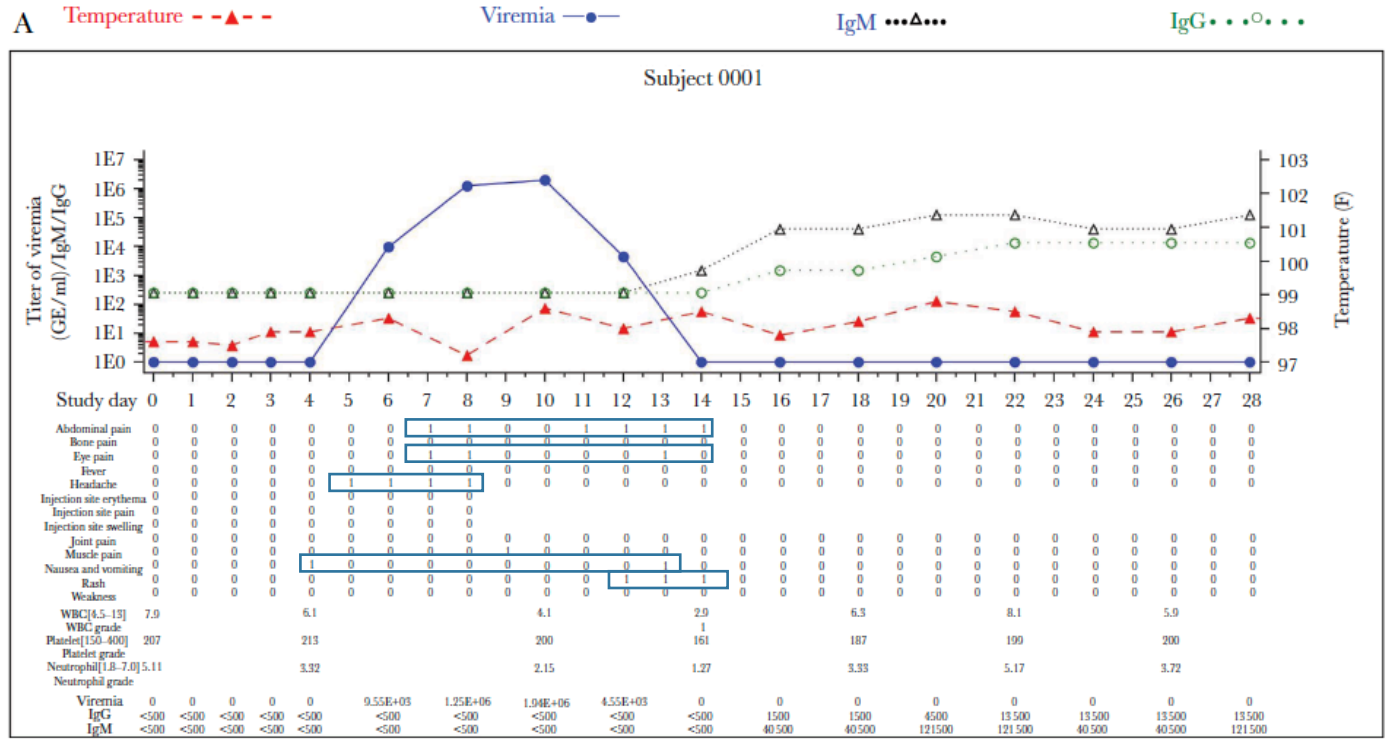
US ARMY CRADA* PROVIDES CONTROL GROUP FOR PROTECT



Phase 1 challenge study conducted by Walter Reed Army Institute of Research and SUNY provides ILA's Phase 2a/b study control data, and enables unprecedented ability to monitor dengue symptoms, including:

- Abdominal & eye pain
- Fever
- Headache
- Nausea and vomiting
- Rash

Island will use the same attenuated virus and approach in its PROTECT study.



Endy et al, J Inf Dis 2021 | * Cooperative Research And Development Agreement: <https://www.doi.gov/techtransfer/crada>



PIPELINE BUILD, OPPORTUNITIES AND MILESTONES



TARGETING KNOWN OR RE-PURPOSABLE DRUGS WITH REDUCED TIME TO MARKET



GALIDESIVIR – Ebola, Marburg, Zika & and many other RNA viruses

- 12 month, **binding** Letter of Intent signed 11 September 2024 (AU)
- Substantial Phase I human safety data
- Proven protective efficacy in a number of lethal animal models
- If proceed to full option agreement, would be seeking to confirm continued access to FDA's **Animal Rule**
- Extensive US government funding to date
- PRV eligible (multiple options)



COMMERCIAL OPPORTUNITIES



BOTH candidates have prophylactic and therapeutic potential



Travellers

Malaria is also a mosquito borne disease and therefore a proxy for other tropical diseases. Market for anti-malarials is expected to reach US\$1B¹ by 2026



Military

Relationship with US Army in place (CRADA, ISLA101). Will continue discussions as programmes advance. Proven interest in both assets.



National Outbreaks

Millions of patients in Latin America & Asia offer potential for sales in disease suppression and treatment during outbreaks of dengue, Zika. Increasing rapidly elsewhere.



Government Stockpiles

Potential for countries to establish civilian and military drug stockpiles as happens with influenza.



Priority Review Vouchers

Last ten PRVs sold for an average of US~\$110M, with potential for ISLA-101 and galidesivir at the time of first FDA approval

1. <https://www.alliedmarketresearch.com/anti-malarial-drug-market>

CORPORATE SNAPSHOT



Key data

Share price (AUD ¹)	\$0.079
Market cap ¹	\$10.1m
Shares on issue ¹	126,782,904
Listed Options ²	32,506,360
Cash ³	\$1.7m

Board of Directors

Dr Paul MacLeman, Executive Chairman
Dr David Foster, CEO and Managing Director
Mr Chris Ntoumenopoulos, Non-Executive Director
Mr Albert Hansen, Non-Executive Director
Dr Anna Lavelle, Non-Executive Director

Recent ILA trading history



Substantial shareholders

Shareholder	Ownership ⁴
Mr Jason Alan Carroll	24,100,000 (19.01%)
Dr William James Garner	22,056,105 (17.40%)
Albert Hansen / Kesa Partners	11,104,034 (8.68%)

Ownership breakdown

- Top 20¹: 72.3%
- Board and management¹: 13.3%

DoD grant funding

- USD \$625k to directly support the Phase 2 + in kind support

1. As at 12 September 2024 | 2. [ILAO Option terms](#): Exercise price of \$0.06 expire 14 March 2025. | 3. As at 30 June 2024 – does not take into consideration cash burn since June 2024 or cash received from options exercised | 4. Shares held per ASX lodged substantial holder notices | Share price data sourced from asx.com.au

KEY MILESTONES**



H1 FY 2024 (Jul – Dec 2023)

- ✓ Key US and Australian patents granted for ISLA-101
- ✓ Obtain HREC (i.e. IRB) approval
- ✓ Screen, enrol and dose volunteers in Single Ascending Dose study
- ✓ Successful progression through Single Ascending Dose study cohorts

H2 FY 2024 (Jan – Jun 2024)

- ✓ Dose final Single Ascending Dose study subject
- ✓ Single Ascending Dose study read out
- ✓ FDA interaction on Phase 2a/b study protocol
- ✓ Pipeline expansion efforts
- ✓ Complete in silico modelling of multiple dosing regimen

H1 FY 2025 (Jul – Dec 2024)

- ✓ Obtain ethics approval for Phase 2 trial
- ✓ **Screening patients in Phase 2a/b trial**
- Subjects dosed in Phase 2a trial
- Data readout from Phase 2a trial
- **Ongoing DD on Galidesivir program**
- **Ongoing discussions with potential partners**

H2 FY 2025 (Jan – Jun 2025)

- Subjects dosed in Phase 2b trial
- Data readout from Phase 2b trial
- End of Phase 2a/b meeting anticipated with FDA
- Plans announced for next steps in clinical programs
- Ongoing discussions with potential partners

** Dates are indicative only, based on best estimates at the time of writing; subject to change.

Island Pharmaceuticals (ASX: ILA)



islandpharmaceuticals.com



[@IslandPharma](https://twitter.com/IslandPharma)



[Island Pharmaceuticals](https://www.linkedin.com/company/island-pharmaceuticals)



pmacleman@islandpharmaceuticals.com

+61 419 401 445

SCIENTIFIC ADVISORY BOARD



Dr Leigh Farrell

Leigh has over 30 years' experience in the biotechnology and pharmaceutical industry and is Head of Health Security Systems Australia, a Division of DMTC Ltd, is a non-executive director of Pro Medicus Ltd, Ena Respiratory Pty Ltd and Axelia Oncology ty Ltd, and is a member of the Walter and Eliza Hall Institute of Medical Research Board Commercialisation Committee and a member of the Independent Advisory Council of Medicines Australia.

Leigh's past appointments include: Senior Vice President, Commercial at Certara USA, Inc where he was responsible for Asia Pacific Commercial and global government engagement for the preparedness, planning and response to major health emergencies; Chairman & COO of d3 Medicine, LLC; Vice President of Business Development at Biota Pharmaceuticals Ltd, Research Manager Johnson & Johnson Research and CEO of Gene Shears Pty Ltd. Leigh holds a PhD in Biochemistry from Monash University.



Prof Stephen Thomas MD

US WRAIR – SUNY Upstate
Professor Stephen Thomas, MD has an international leadership role as Lead Principal Investigator for Pfizer/BioNTech global Phase III COVID-19 vaccine trial now being deployed globally.

Prof. Thomas is a world-renowned virologist and vaccinologist and has authored numerous papers and articles on dengue fever, Zika and many other infectious diseases.

Chief, Division Of Infectious Diseases, New York Upstate Medical University; Professor of Medicine, Professor of Microbiology & Immunology, and Infectious Diseases physician-scientist from the State University of New York (SUNY), Upstate Medical University; Chief, Division of Infectious Diseases and Director, Institute for Global Health and Translational Science (IGHTS.)

He had twenty years in the U.S. Army Medical Corps serving at the Walter Reed Army Institute of Research (WRAIR.)



Dr Amy Patick

BMS – Mayo Clinic
Amy Patick is a scientific consultant with deep expertise in antiviral drug discovery, development and viral resistance with broad know how in emerging virus epidemics and translational medicine.

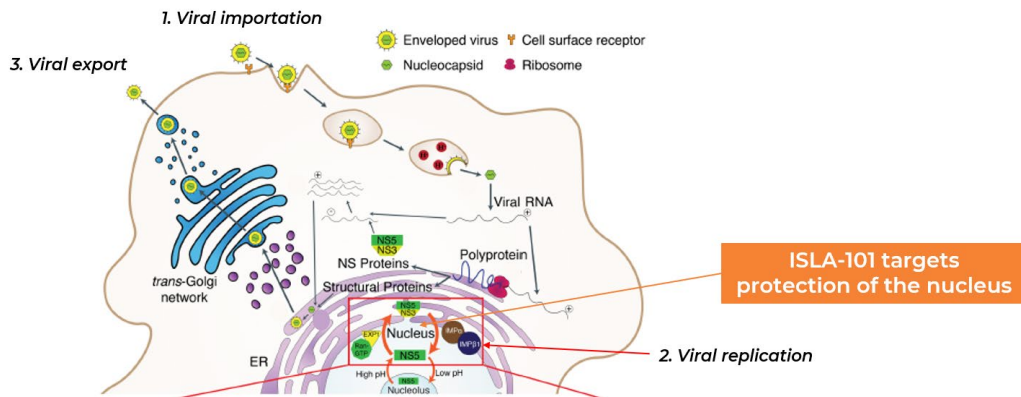
Previously, Dr. Patick has served as Vice President, Research at Adamas Pharmaceuticals, Vice President, Biological Sciences at Genelabs Technologies, Head of the Antiviral Biology Therapeutic Area at Pfizer, Inc. and Research Scientist at Bristol-Myers Squibb Company. Dr. Patick has also served as President for the International Society of Antiviral Research.

Dr. Patick was a postdoctoral fellow in immunology at the Mayo Clinic/Foundation in Rochester, MN and received her PhD in Medical Microbiology from the University of Wisconsin, Madison.

ISLA-101 PREVENTS VIRAL REPLICATION



Mechanism of action (how it works)

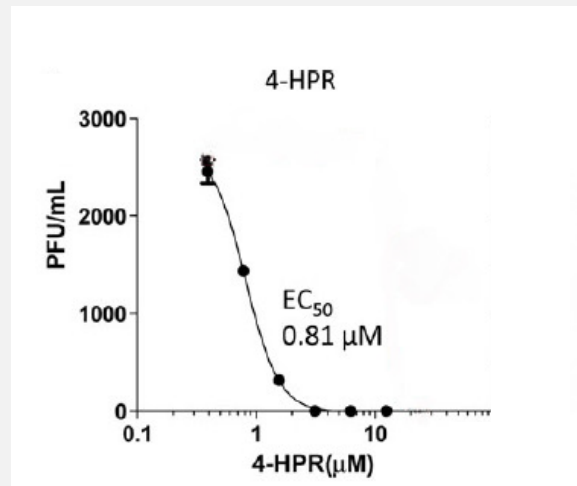


ISLA-101 inhibits propagation of flaviviruses

- To replicate, the virus needs to hijack the nucleus of the host cell
- Studies demonstrated ISLA-101 prevents this, therefore preventing virus replication
- Same mechanism of action for a therapeutic or prophylactic – either before or after exposure to the virus

1. Fraser et al. J. Infect. Dis 2014

ISLA-101 reduces viral load¹



Above: dose response showing ISLA-101's ability to protect against dengue infection

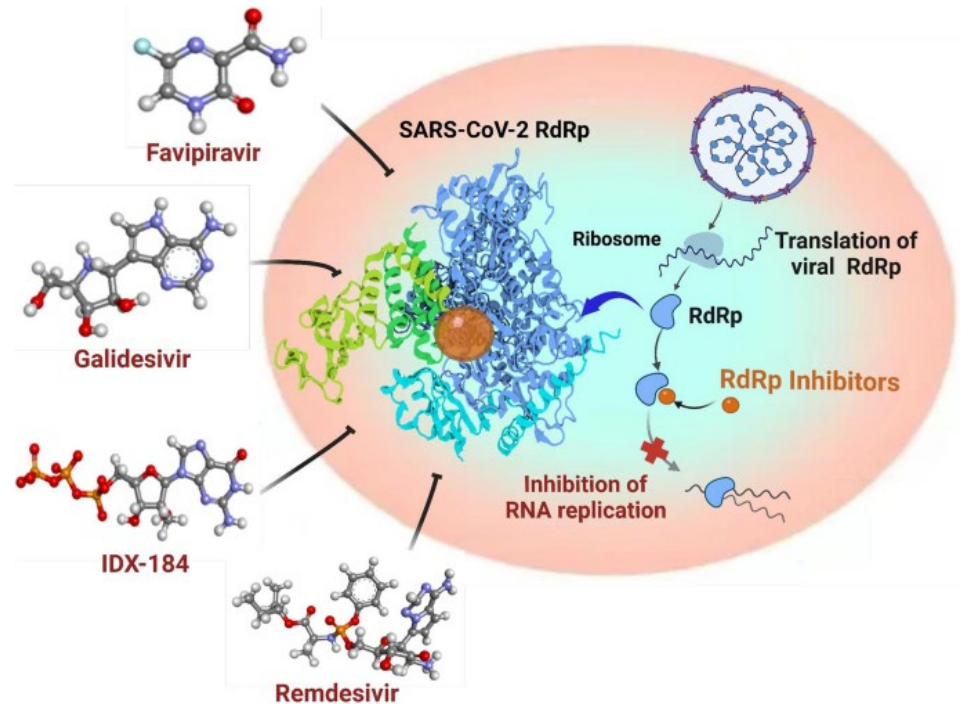
- In freshly isolated human cells, ISLA-101 was shown to potently reduce viral infection with a sub micromolar EC_{50}
- Island's SAD study was designed to also investigate the ability to achieve appropriate blood concentrations in healthy human volunteers (slide 16)

GALIDESIVIR PREVENTS VIRAL REPLICATION



Galidesivir inhibits propagation of RNA viruses

- RNA-dependent RNA polymerase (RdRp) is crucial in viral replication and transcription
- Catalyses viral RNA synthesis and is the therapeutic target of Galidesivir



PLAYERS IN THE MEDICAL COUNTERMEASURES SPACE



- BioFactura
- BioFire Defense
- Certara
- Emergent BioSolutions
- Evotec SE
- IDbyDNA (DIGET program)
- Juxtopia
- DARPA Panacea Program
- ARMR
- JnJ Blue Knight Consortium

Programs backed by BARDA and/or NIAID



<https://globalbiodefense.com>